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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,678	09/15/2003	John P. Troup	N-326663A/USN	1877

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,678	TROUP ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *6,12 and 18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election/Restriction filed on October 04, 2007 is acknowledged. Claims 1-22 are pending in this application.

Restriction

1. Applicant's election with traverse of Group I (claims 1-17) drawn to a composition comprising amino acids in free form and/or salt form, and the election of species methionine for amino acid, EPA (eicosapentaenoic acid) for n-3 polyunsaturated fatty acids, and tocopherol for vitamin E component in the reply filed on October 04, 2007 is acknowledged. The traversal is on the ground(s) that composition and its limited uses would not create a serious burden on the Examiner. Applicant argues that the composition and its use is intimately related and that a search of references concerning the composition could include a simultaneous search of the references concerning the intended use of claims 18-22. Additionally, Applicant argues that the number of species of amino acids, intact proteins, n-3 polyunsaturated fatty acids, and vitamin E is more than a reasonable number of species. This is not found persuasive because as described in the previous office action, the composition and the method inventions are patentably independent and distinct because a materially different composition can be used to ameliorate a condition associated with cachexia and/or anorexia and stimulate muscle protein synthesis, for example, carbohydrates and insulin like growth factor I (IGF-I) can enhance muscle protein synthesis and corticosteroids can be used to ameliorate a condition associated with cachexia and anorexia. Furthermore, the two

method inventions are patentably independent and distinct because not everyone needing muscle protein synthesis stimulation is suffering from a condition associated with cachexia and/or anorexia. Additionally, the species are independent and distinct due to their different structures. For example, as described in the previous office action, amino acids isoleucine and phenylalanine have different structures, and a search for one would not lead to the other. Furthermore, the inventions restricted are patentably distinct. The search for each of the inventions is not co-extensive particularly with regard to the literature search. Burden consists not only of specific searching of classes and subclasses, but also of searching multiple databases for foreign references and literature searches. Burden also resides in the examination of independent claim sets for clarity, enablement, and double patenting issues. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application and the restriction for examination purposes as indicated above is deemed proper.

2. The requirement is still deemed proper and is therefore made FINAL. Claims 6 and 12 are withdrawn from further consideration as being drawn to nonelected species. Claim 6 is withdrawn because the Applicant was required to elect different amino acid species (all essential amino acid) and conditionally essential amino acids, and the Applicant elected methionine, which does not include arginine. Claims 18-22 are withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to

nonelected inventions, there being no allowable generic or linking claim. Claims 1-5, 7-11, and 13-17 are examined on the merits in this office action.

Objection-Minor Informalities

3. The title is objected to because the title is not descriptive. The title is limited to 2-7 words maximum. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. The specification is objected to because there seems to be a typographical error at paragraph [0091]. At line 6 of the paragraph, it recites, "on one occasion and 15 9 of whey protein on another." By reading from line 4th line of the paragraph, it recites, "15 g of free essential amino acids", it would appear that the line 6 should read, "one occasion and 15 g of whey protein on another." Applicant is advised to correct this error and any other typographical error that may be present in the specification.

Rejection-35 U.S.C. 112, 2nd

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 3 recites, "wherein total essential and, optionally, conditionally essential amino acids are present in an amount of about 55% to about 75% by weight based on

the weight of total amino acids." This phrase "weight based on the weight of total amino acids" is unclear. The claim is drawn to a composition comprising essential and, optionally, conditionally essential amino acid (represented here as "A" for clarification) and an intact protein (represented here as "B" for clarification). It is unclear if an amount of about 55% to about 75% by weight implies all of essential amino acid (including conditionally essential) cited in "A" and any amino acid present in the intact protein "B" or if the weight implies just the subset "A". In other words, it is unclear if an amount of about 55% to about 75% by weight implies A-B together or just A.

8. Claim 4 recites, "The composition of claim 3, wherein the essential and, optionally, conditionally essential amino acids comprises leucine and at least one of isoleucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine, or histidine." It is unclear what is meant by "conditionally essential amino acids", since all of the amino acids listed are essential amino acids. Furthermore, www.feinberg.northwestern.edu/nutrition/factsheets/protein.html recites that essential amino acids are His, Ile, Leu, Lys, Met, Phe, Thr, Trp, Tyr, Val, Ser, Tyr and nonessential amino acids are Ala, Arg, Asp, Cys, Glu, Gln, Gly and Pro. Since there are discrepancies as to what are considered "essential' and "nonessential" amino acids, it is further unclear what represents "conditionally essential amino acids".

Rejection-35 U.S.C. 112, 1st

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 3-5, 7-11 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

11. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

12. Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

13. The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872 F.2d at 1012, 10 USPQ2d at 1618.

14. In the instant case, the claims are drawn to a composition comprising, a) essential and, optionally, conditionally essential amino acids in free from and/or salt

form, and b) intact protein, wherein total essential and optionally, conditionally essential amino acids are present in an amount of about 55% to about 75% by weight based on the weight of total amino acids and a kit comprising the above and a second composition comprising an anti-cancer drug. The generic statements intact protein and anti-cancer drug do not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

15. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claims 3, 8 and 17 are broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide or a peptide-like molecule that can form cross-linking or can be cross-linked to form an intact protein, and make up the class of intact protein. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of

derivatives. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as a peptide or a peptide-like molecule or other peptidic molecules that can be cross-linked, and other synthetic peptide or peptide-like molecule that can form peptide bonds and function as intact protein.

16. The specification is limited to the peptide or peptide-like molecules that belong to the same class of protein, casein, whey protein, soy protein, collagen or wheat protein. The working example the comparison of free essential amino acids (leucine, isoleucine, methionine, phenylalanine, histidine, lysine, and threonine) on one occasion and 15 g (?) of whey protein on another (see paragraph [0091]). The specification discloses that "the compositions may further comprise conditionally essential amino acids in free and/or in salt from and/or in form of intact protein..." (see for example paragraphs [0025], [0027], [0029] and so on). The specification further discloses that n-3 polyunsaturated fatty acids, including, but not limited to α-linolenic acid (LNA), eicosapentaenoic acid (EPA), and docosahexanenoic acid (DHA), either alone or in combination with each other (see paragraph [0040]). The specification further discloses that the invention may be combined with anti-cancer drugs, such as 5-fluorouracil, mitomycin-C, adriamycin, chloroethyl nitrosureas and methotrexate (see paragraph [0077]). The specification does not describe any other intact protein, such as synthetic polymers comprising repeating polypeptide units or any other proteins in plants, vegetables and meat that are cross-linked (such as hemoglobin), or any other type of peptide or peptide-like molecule that function as intact proteins. The specification does

not disclose any other n-3 polyunsaturated fatty acids, such as C18:4n3, C20:4n3, DPA (C22:5n3), C24:5n3, C24:6n3, variants, derivatives and so on. The specification does not disclose any peptide anti-cancer drugs, such as enzyme L-asparaginase and any other antibiotics and small molecules other than 5-fluorouracil, methotrexate and others. Description of casein, whey protein, soy protein, collagen or wheat protein is not sufficient to encompass numerous other proteins that belong to the same genus. Description of 5-fluorouracil, mitomycin-C, adriamycin, chloroethyl nitrosureas and methotrexate is not enough to encompass numerous other peptides, proteins, and small molecules that belong to the same genus, anti-cancer drugs. For example, there are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up the genus. Since an intact protein can be made up of any amino acid sequences, there are vast numbers of possibilities. There are 20 naturally occurring amino acids, and there are 5 conditionally essential amino acids (arginine, cysteine, glycine, glutamine, and tyrosine). These amino acids can form any amino acid sequences. Furthermore, since there are 9 essential amino acids, these can further increase the numbers of the intact proteins that are possible. There are vast numbers of n-3 polyunsaturated fatty acids and their derivatives and variants. Additionally, there are innumerable possible anti-cancer drugs that are made up of amino acids, small molecules, amino acid and peptide mimetics and so on. There is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

17. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Rejection-35 U.S.C. 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Madsen et al (US Patent # 4898879).

20. The instant claims are drawn to a composition comprising leucine and at least one of isoleucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine, or histidine in free and/or salt from, wherein leucine, in free and/or salt form, is present in an amount of at least 10% to about 35 % by weight based on the weight of total amino acids.

21. Madsen et al teach nutritional compositions comprising L-leucine (about from 19.4 to 19.8 %), L-isoleucine (16.2 to 16.4%), L-valine (14.5% to 14.8%), L-lysine (10.2% to 10.3%), L-methionine (1.1 to 1.2%) and so on (see column 3, lines 10-25). This reads on claims 1-2, since the composition comprises about 19.4 to 19.8% of leucine and about 1.1 to 1.2% methionine, and at least 19.8% is about at least 20%, this reads on claims 1-2. The reference also teaches that the essential amino acids should comprise about from 60 to 75% by weight of the total amino acids in the composition (see column 3, lines 32-34).

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

22. Claims 3-5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Hageman et al (US Patent # 6420342).

23. The instant claims are drawn to a composition comprising a) essential and, optionally, conditionally essential amino acids in free from and/or salt form, and b) intact protein, wherein total essential and, optionally, conditionally essential amino acids are present in an amount of about 55% to about 75% by weight based on the weight of total

amino acids, and total leucine is present in an amount of about 20% to about 35% by weight based on the weight of total amino acids.

24. Hageman et al teach a nutritional, pharmaceutical or dietetic preparation can be manufactured in dry form, as bar, as powder, as tablet, and cookie or as cereal (see column 5, lines 60-63). The reference further teaches for products for sportsmen the following mixtures of amino acids appeared to be especially beneficial for muscle growth, when consumed in an amount of more than 2 and preferably more than 4 g per daily dose: 3-10 wt % histidine, 5-15 wt % isoleucine, 10-23 wt % leucine, 10-23 wt % lysine, 5-15 wt % methionine, 5-15 wt % phenylalanine, and 5-15 wt % threonine (see column 6, lines 59-67 and column 7, line 1). Furthermore, the reference teaches that when proteins are included in the nutritional preparations, the amount that is included depends on the application (see column 6, lines 39-41) and the proteins are proteins of dairy, vegetable or animal origin, such as skimmed milk powder, whey powder, egg white powder, potato protein, soy protein, etc, or hydrolysates, or mixtures thereof (see column 6, lines 27-32). This reads on claims 3-5 and 7.

25. Claims 3-5 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Hageman et al (US Patent # 6420342).

26. The teachings of Hageman et al are described supra.

27. Claims 3-4, 7-11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbruzzese et al (US Patent # 6387883).

28. The instant claims are drawn to a composition comprising a) essential and, optionally, conditionally essential amino acids in free form and/or salt form, and b) intact protein, wherein total essential and, optionally, conditionally essential amino acids are present in an amount of about 55% to about 75% by weight based on the weight of total amino acids, and n-3 polyunsaturated fatty acid (EPA) and tocopherol.

29. Abbruzzese et al teach nutritional compositions for the prevention and treatment of cachexia and anorexia, comprising effective amounts of omega-3 fatty acids (LNA, DPA, DHA and so on); branched-chain amino acids valine, leucine, isoleucine or mixtures thereof; and antioxidant system selected from beta-carotene, vitamin C, vitamin E, selenium, or mixtures thereof (see abstract). The reference teaches that the total amount of branched-chain amino acids (BCAA) useful is about 15-50g/100g protein (i.e. percent), and would contain up to about 8 g BCAAs per 16 grams of total protein. The daily delivery of BCAAs is about 5-26 g (see column 9, lines 26-29). This reads on claims 3-4. The reference teaches that leucine in the amount of 9.08 g (9.08%) and methionine in the amount of 2.78 g (2.78%). This meets the limitation of claims 7 and 15. The reference teaches that EPA is in the amount of 1.09 g and DHA is in the amount of 0.46 g (see Table 3). This reads on claims 8-10. Furthermore, the reference teaches the d-alpha-tocopherol (vitamin E, IU) in the amount of 300.00 Qty/Liter (see Table 6) or 10.65 kg (Table 11). The reference further teaches that composition to treat ulcerative colitis include a protein source that can be intact or hydrolyzed proteins of high biological value (see column 3, lines 7-9) and teaches 75% whey protein concentrate as one of the ingredients (see Table 7). This reads on claim 3 in part.

30. Claims 3-4, 7-11 and 15 are rejected under 35 U.S.C. 102(a) as being anticipated by Abbruzzese et al (US Patent # 6387883).

31. The teachings of Abbruzzese et al are described supra.

Rejection-35 U.S.C. 103

32. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

33. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

34. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

35. Claims 3-4, 7-11, 14 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbruzzese et al (US Patent # 6387883).

36. The instant claims are drawn to a composition comprising a) essential and, optionally, conditionally essential amino acids in free form and/or salt from, and b) intact protein, wherein total essential and, optionally, conditionally essential amino acids are present in an amount of about 55% to about 75% by weight based on the weight of total amino acids, and further comprising tocopherol in the amount about 50 mg per serving or at least 150 mg per daily dose, and the composition comprising from about 6 g to about 18 g amino acids in free and/or salt form per daily does or 6 g to about 21 g total essential and/or conditionally essential amino acid per serving.

37. The teachings of Abbruzzese et al are described supra. The difference between the reference and the instant claims are that the reference do not teach tocopherol in an amount about 50 mg per serving or at least 150 mg per daily dose, and amino acids in 6 g to about 18 g in free and/or salt from per daily dose, and 6 g to about 21 g total essential and/or conditionally essential amino acid per serving.

38. Therefore, it would have been obvious to one of ordinary skilled in the art to optimize the conditions of Abbruzzese et al to produce a nutritional composition comprising essential and non-essential amino acids and PUFA such as EPA, since the prior art teaches nutritional composition for treating cancer cachexia. There is a reasonable expectation of success, since "it is the normal desire of scientists or artisans

to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is optimum combination of percentages". The MEPE states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. *"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* In re Aller, *220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)* (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*"); In re Hoeschele, *406 F.2d 1403, 160 USPQ 809 (CCPA 1969)* (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362

(Fed. Cir. 1997). Therefore, there is a reasonable expectation of success to optimize the concentrations of the tocopherol and essential amino acid concentration, since it is "*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages*" and one of ordinary skill in the art would experiment with different concentrations to produce the optimal product.

Conclusion

39. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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